4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0902]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions; Amendments and Easily Correctable Deficiencies Under the Generic Drug User Fee Amendments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA." The guidance document is intended to assist applicants in preparing to submit to FDA amendments to abbreviated new drug applications (ANDAs) or prior approval supplements (PASs) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), by explaining how the Generic Drug User Fee Amendments of 2012 (GDUFA) performance metric goals apply to these submissions. When finalized, this guidance will replace the December 2001 guidance for industry entitled "Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications" in consideration of the new amendment review tier system and performance goals under GDUFA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, Elizabeth.Giaquinto@fda.hhs.gov or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA." On July 9,

2012, GDUFA (Pub. L. 112-144, Title III) was signed into law by the President to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to certain performance goals and procedures for the review of amendments submitted to original ANDAs and PASs filed on or after October 1, 2014.

This draft guidance describes how FDA intends to classify major amendments, minor amendments, and easily correctable deficiencies (ECDs). Specifically, the draft guidance defines the types of amendments and describes the GDUFA performance metric goals for the amendment tiers, the process for submitting amendments, and dispute resolution procedures regarding amendment classifications.

In accordance with the Commitment Letter, the GDUFA performance metrics described in the draft guidance only apply to amendments to original ANDAs and PASs submitted on or after October 1, 2014, and do not apply to amendments submitted on or after October 1, 2014, that amend original ANDAs or PASs submitted before October 1, 2014.

Elsewhere in this issue of the Federal Register, FDA is announcing another draft guidance entitled "ANDA Submissions--Prior Approval Supplements Under GDUFA," which describes FDA's performance metric goals and clarifies how FDA will handle a PAS and amendments to a PAS for an ANDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency□s current thinking on "ANDA Submissions--Amendments and Easily Correctable Deficiencies Under GDUFA." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.96 have been approved under OMB control number 0910-0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or http://www.regulations.gov.

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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